UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/889,321	07/13/2001	Yousuke Takahama	31671-173265	2334

26694 7590 01/24/2007

VENABLE LLP
P.O. BOX 34385
WASHINGTON, DC 20043-9998

EXAMINER	
WEHBE, ANNE MARIE SABRINA	
ART UNIT	**PAPER NUMBER**
1633	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/24/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/889,321	TAKAHAMA, YOUSUKE	
	Examiner	Art Unit	
	Anne Marie S. Wehbe	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 October 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7 and 13-20* is/are pending in the application.

4a) Of the above claim(s) *13-19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7 and 20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendment received on 10/27/06 has been entered. Claims 8-12 are canceled and new claim 20 has been added. Claims 1-7, and 13-20 are pending in the instant application.

This application contains claims 13-19 drawn to an invention non-elected without traverse in the response received on 11/03/03. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claims 1-7 and 20 are currently under examination. An action on the merits follows.

Those sections of Title 35, US code, not included in this action can be found in the previous office action.

Claim Rejections - 35 USC § 112

The rejection of claims 1-12 under 35 U.S.C. 112, first paragraph, for new matter added to the claims filed on 8/19/04 is maintained over pending and new claims 1-7 and 20. Applicant's Declaration by Emiko Oku declares that the translation of the Japanese priority document into English did not utilize the most correct choice of words in translating the Japanese term "yojaku". Emiko Oku declares that "yojaku" should have been translated as "immature" not "fetal" in the instant specification. While the Office accepts the Declaration of Emiko Oku as evidence of a mistranslation, the applicant has not amended the specification to replace the

incorrect term "fetal" with the word "immature". As such the as filed specification, with its mistranslation, continues to written description for "immature" T lymphocytes as claimed.

This rejection can be overcome by amendment of the specification to replace "fetal"T lymphocyte(s) with "immature" T lymphocyte(s). In view of the numerous recitations of "fetal T lymphocyte(s)" in the as filed specification, it is suggested that applicant file a substitute specification. The substitute specification must be submitted with markings showing all the changes relative to the immediate prior version of the specification of record. The text of any added subject matter must be shown by underlining the added text. The text of any deleted matter must be shown by strike-through except that double brackets placed before and after the deleted characters may be used to show deletion of five or fewer consecutive characters. The text of any deleted subject matter must be shown by being placed within double brackets if strike-through cannot be easily perceived. An accompanying clean version (without markings) and a statement that the substitute specification contains no new matter must also be supplied. Numbering the paragraphs of the specification of record is not considered a change that must be shown.

The rejection of claims 1-12 under 35 U.S.C. 112, first paragraph, for scope of enablement is maintained in part over pending and new claims 1-7 and 20. Applicant's arguments have been fully considered by have not been found persuasive in overcoming the instant rejection of record for reasons discussed in detail below.

The previous office action stated that the specification, while being enabling for 1) methods of acquiring immunological tolerance to a foreign DNA and/or its expression product

comprising: providing a fetal T lymphocyte transfected with the foreign DNA, irradiating a host mammal in order to transiently suppress T lymphocytes, and introducing the transfected fetal T lymphocyte into the thymus of the host mammal, wherein the introduced fetal T lymphocyte induces immunological tolerance to the foreign DNA and/or its expression product and 2) methods of sustaining the expression of a foreign gene by avoiding immune responses caused by the foreign gene and/or its expression product comprising providing a fetal T lymphocyte transfected with the foreign gene, irradiating a host mammal in order to transiently suppress T lymphocytes, introducing the transfected fetal T lymphocyte into the thymus of the host mammal, wherein the introduced fetal T lymphocyte induces immunological tolerance to the foreign gene and its expression product, and administering the foreign gene, wherein the expression of the gene product is sustained, does not reasonably provide enablement for said methods wherein the transfected T lymphocyte is not a fetal T lymphocyte, wherein the host mammal has not been irradiated to suppress existing T lymphocytes, or wherein the gene product expressed has a therapeutic effect. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Applicant's cancellation of claims 8-12 overcomes the rejection of record related to the lack of enablement for sustaining a gene therapeutic effect in gene therapy. Further, the amendment to claim 1 which adds the limitation that mature T lymphocytes in the thymus are suppressed overcomes the lack of enablement for practicing the method without suppression of existing T lymphocytes.

One issue remains, the lack of enablement for using any immature T lymphocyte other than a fetal T lymphocyte. As noted above, while the Declaration of Emiko Oku provides evidence for a mistranslation of the term "yojaku", which should have been translated as "immature" not "fetal" in the instant specification, the instant specification has not been amended to correct this error. The applicant argues that the working examples provides evidence that the method as claimed is enabled by the specification. It is noted that applicant's arguments consistently refer to "immature" T lymphocytes although the specification refers to "fetal" T lymphocytes. However, assuming applicant's amends the specification to recite "immature T lymphocyte" not "fetal T lymphocyte", the specification would still fail to provide an enabling disclosure for practicing the instant methods as claimed with the breadth of immature T lymphocytes. The previous office action stated that the claims as written broadly recite acquiring immunological tolerance to a foreign DNA and/or its expression product comprising introducing a transfected immature T lymphocyte into the thymus. The term "immature T lymphocyte" is broad and encompasses any non-mature T cell, including fetal cells and adult cells. However, the specification does not recite the term "immature T lymphocyte" or provide any description of what specific characteristics such as cell would possess. The specification only provides specific guidance for using fetal T lymphocytes to tolerize immune responses in a non-human mammal. This includes the working examples, which are limited to the use of fetal T lymphocytes derived from a day 14-18 mouse embryo. Amendment of the specification to recite "immature" instead of "fetal" would not change the fact that T lymphocytes derived from a day 14-18 mouse embryo are fetal T lymphocytes, not adult immature lymphocytes. Thus, the specification as filed fails to provide any guidance as the characteristics of an "immature" T lymphocyte that would allow it

to be used successfully to induce immunological tolerance in the thymus, and further provides no guidance or evidence that any T lymphocyte other than a T lymphocyte derived from a day 14-18 embryo, i.e. a fetal T lymphocytes, which can be transfected/transduced with foreign DNA and induce immunological tolerance to foreign DNA and its expression product when introduced into the thymus of a mammal. Thus, based on the breadth of the claims, and the lack of specific guidance provided by the specification, the specification fails to provide an enabling disclosure for how to identify and isolate any "immature" T lymphocyte, and to use that immature T cell to induce immunological tolerance to a foreign gene or gene product without undue experimentation. Thus, the rejection of record stands.

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Wehbé, Ph.D., whose telephone number is (571) 272-0737. If the examiner is not available, the examiner's supervisor, Joseph Woitach, can be reached at (571) 272-0739. For all official communications, **the new technology center fax number is (571) 273-8300**. Please note that all official communications and responses sent by fax must be directed to the technology center fax number. For informal, non-official communications only, the examiner's direct fax number is (571) 273-0737. For any inquiry of a general nature, please call (571) 272-0547.

The applicant can also consult the USPTO's Patent Application Information Retrieval system (PAIR) on the internet for patent application status and history information, and for electronic images of applications. For questions or problems related to PAIR, please call the USPTO Patent Electronic Business Center (Patent EBC) toll free at 1-866-217-9197. Representatives are available daily from 6am to midnight (EST). When calling please have your application serial number or patent number available. For all other customer support, please call the USPTO call center (UCC) at 1-800-786-9199.

Dr. A.M.S. Wehbé

ANNE M. WEHBE' PH.D
PRIMARY EXAMINER